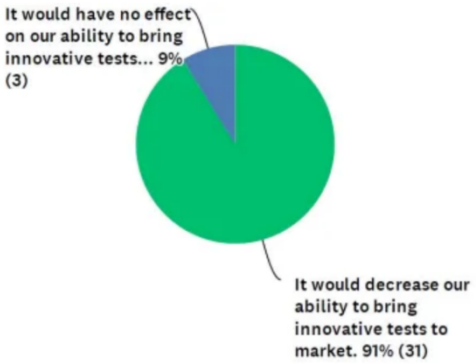
COALITION FOR INNOVATIVE LABORATORY TESTING

WHY DO NEARLY ALL CLINICAL LABS IN THE U.S. STRONGLY OPPOSE THE VALID ACT?

- **The VALID Act would dramatically reduce innovation in laboratory testing.**
  - More than 90% of laboratories responding to a March 2022 survey by a leading industry publication strongly agreed that if the VALID Act becomes law it will decrease their ability to bring innovative tests to market.
  - Over 65 leaders of clinical laboratories and diagnostics companies from throughout the U.S. that develop innovative lab tests across the disease spectrum signed a letter to Congress declaring that the VALID Act "would force smaller labs to abandon development and commercialization of tests that could otherwise improve patient outcomes and reduce healthcare costs."



- **The VALID Act will force hundreds of smaller labs to downsize or close leaving our nation unprepared for future Covid variants or new pandemics.**
  - The pandemic demonstrated the compelling need for locally based clinical labs that are nimble and fast acting in an emergency to generate test results in hours not days. Many of these labs will disappear if the VALID Act becomes law, leaving our nation vulnerable.

- **The VALID Act creates mandates that are duplicative of the plethora of regulations already in place by federal and state agencies and medical organizations.**
  - The regulations that would be implemented under the VALID Act would impose "tremendous and wholly unnecessary burdens on labs." (Letter to Congress). Under current CLIA rules, the performance of lab developed tests (LDTs) are subject to extensive controls and ongoing inspection and accreditation requirements from the states and CMS, which maintain the quality of the laboratory's testing products and processes. Additionally, some states like New York and medical organizations like the College of American Pathologists (CAP) evaluation the clinical validity of individual tests.
  - The aforementioned industry survey revealed that 80% of respondents believed that regulation of LDTs by the FDA were not needed. 88% of commercial labs surveyed agreed that modernizing CLIA requirements for LDTs, as called for in the VITAL Act were preferred over FDA regulations.

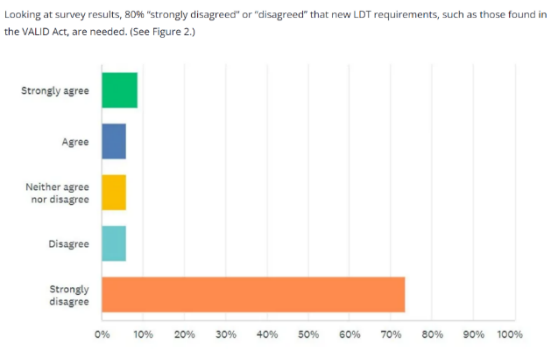


Figure 2: "FDA pre-market approval of LDTs should be required, as proposed in the VALID Act."